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09/638,693	08/15/2000	Geert Maertens	2752-15	2013

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EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/638,693

Applicant(s)

MAERTENS ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56, 59 and 75-85 is/are pending in the application.
- 4a) Of the above claim(s) 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56, 59, 76 and 77 is/are rejected.
- 7) ☒ Claim(s) 78-85 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/19/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claim 75 stands withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 23, 2003. Applicants assert (response filed February 1, 2005 (copy resubmitted December 19, 2006) pages 26-27) that the SEQ ID NOs mentioned in claim 75 are contained within SEQ ID NO: 36. This assertion is incorrect. A Gly appears in SEQ ID NO: 36, residue 99 while the corresponding amino acid residue in SEQ ID NOs: 99 and 100 is Glu.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56, 59, and 76 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of Flores et al (Nucleic Acids Re. 18, 901 (1990), see especially page 905, Figure 2, line 14 of the amino acid sequence), Shuldiner et al (J. Biol. Chem. 264: 9428 (1989) see especially page 9430, Figure 2, Sequence II, lines 2-3 of the amino acid sequence), Yuan et al (Proc. Natl. Acad. Sci. USA 80: 1169 (1983) see especially page 1172, Figure 2, amino acid residues 102-107), Williams et al (Biochemistry 31: 9768 (1992) see especially page 9771, Figure 2, amino acid residues 340-345), Horie et al (Biochemistry 106: 1 (1989) see especially page 3, Figure 3, L1HsTs, third line of the sequence), or Rosel et al (J. Virol. 56: 830 (1985) see especially page 835, Figure 5, amino acids corresponding to nucleotides 1371-1388). Each of the references discloses a polypeptide that shares at least 5 contiguous amino acids with the polypeptides mentioned in the claims. See the following alignments.

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**Flores et al (Nucleic Acids Re. 18, 901 (1990))**

## RESULT 77

## QQECD7

tnsE protein - Escherichia coli transposon Tn7

C;Species: Escherichia coli

C;Date: 30-Jun-1988 #sequence\_revision 30-Jun-1988 #text\_change 09-Jul-2004

C;Accession: A25543; S12641; S06770

R;Smith, G.M.; Jones, P.

Nucleic Acids Res. 14, 7915-7927, 1986

A;Title: Tn7 transposition: a multigene process. Identification of a regulatory gene product.

A;Reference number: A93644; MUID:87040763; PMID:3022239

A;Accession: A25543

A;Molecule type: DNA

A;Residues: 1-538 &lt;SMI&gt;

A;Cross-references: UNIPROT:P05845; UNIPARC:UPI0000000F5C; GB:X04534;

NID:g43752; PIDN:CAB56509.1; PID:g5921493

R;Flores, C.; Qadri, M.I.; Lichtenstein, C.

Nucleic Acids Res. 18, 901-911, 1990

A;Title: DNA sequence analysis of five genes; tnsA, B, C, D and E, required for Tn7 transposition.

A;Reference number: S12637; MUID:90192166; PMID:2156235

A;Accession: S12641

A;Molecule type: DNA

A;Residues: 1-538 &lt;FLO&gt;

A;Cross-references: UNIPARC:UPI0000000F5C; EMBL:X17693; NID:g43755;

PIDN:CAA35687.1; PID:g581281

A;Note: the authors translated the initiation codon GTG for residue 1 as Val

C;Genetics:

A;Gene: tnsE

A;Start codon: GTG

C;Function:

A;Description: required for the transposition of transposon Tn7

C;Superfamily: tnsE protein

C;Keywords: DNA binding; transposition

Query Match 5.9%; Score 7; DB 1; Length 538;  
Best Local Similarity 100.0%; Pred. No. 77;  
Matches 7; Conservative 0; Mismatches 0; Indels 0; Gaps  
0;

Qy 17 LGGVLAA 23  
|||  
Db 363 LGGVLAA 369

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Shuldiner et al (J. Biol. Chem. 264: 9428 (1989))

## RESULT 140

IPXL2

insulin II precursor - African clawed frog

C;Species: Xenopus laevis (African clawed frog)

C;Date: 30-Jun-1991 #sequence\_revision 30-Jun-1991 #text\_change 09-Jul-2004

C;Accession: B33847; S13537

**R;Shuldiner, A.R.; Phillips, S.; Roberts Jr., C.T.; LeRoith, D.; Roth, J.  
J. Biol. Chem. 264, 9428-9432, 1989**

A;Title: Xenopus laevis contains two nonallelic preproinsulin genes. cDNA cloning and evolutionary perspective.

A;Reference number: A33847; MUID:89255444; PMID:2722842

A;Accession: B33847

A;Molecule type: mRNA

A;Residues: 1-106 &lt;SHU1&gt;

A;Cross-references: UNIPROT:P12707; UNIPARC:UPI000012D6A3; GB:M24442;

GB:J04796; NID:g214534; PIDN:AAA49887.1; PID:g214535

R;Shuldiner, A.R.; Bennett, C.; Robinson, E.A.; Roth, J.

Endocrinology 125, 469-477, 1989

A;Title: Isolation and characterization of two different insulins from an amphibian, Xenopus laevis.

A;Reference number: S07199; MUID:89289601; PMID:2661211

A;Accession: S13537

A;Molecule type: protein

A;Residues: 24-53;86-106 &lt;SHU2&gt;

A;Cross-references: UNIPARC:UPI000017355F; UNIPARC:UPI0000173560

C;Superfamily: insulin

C;Keywords: hormone; pancreas

F;1-23/Domain: signal sequence #status predicted &lt;SIG&gt;

F;24-53/Domain: insulin chain B #status experimental &lt;BCH&gt;

F;24-53,86-106/Product: insulin #status experimental &lt;MAT&gt;

F;56-83/Domain: connecting peptide #status predicted &lt;CPEP&gt;

F;86-106/Domain: insulin chain A #status experimental &lt;ACH&gt;

F;30-92,42-105,91-96/Disulfide bonds: #status predicted

Query Match 5.1%; Score 6; DB 1; Length 106;

Best Local Similarity 100.0%; Pred. No. 1.9e+02;

Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 72 IEQAQV 77

|||||

Db 57 IEQAQV 62

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Yuan et al (Proc. Natl. Acad. Sci. USA 80: 1169 (1983))

## RESULT 460

S19172

cytochrome P450 2B4 - rat (fragments)

N;Alternate names: cytochrome P450 LM2

N;Contains: oxidoreductase (EC 1.-.-.-)

C;Species: Rattus norvegicus (Norway rat)

C;Date: 22-Nov-1993 #sequence\_revision 21-Jul-1995 #text\_change 09-Jul-2004

C;Accession: S19172

R;Yuan, P.M.; Ryan, D.E.; Levin, W.; Shively, J.E.

Proc. Natl. Acad. Sci. U.S.A. 80, 1169-1173, 1983

A;Title: Identification and localization of amino acid substitutions between two phenobarbital-inducible rat hepatic microsomal cytochromes P-450 by micro sequence analyses.

A;Reference number: S19172; MUID:83144040; PMID:6572377

A;Accession: S19172

A;Status: preliminary

A;Molecule type: protein

A;Residues: 1-158;159-200;201-310;311-367 &lt;YUA&gt;

A;Cross-references: UNIPROT:Q7M0C4; UNIPARC:UPI0000174CD0;

UNIPARC:UPI0000174CD1; UNIPARC:UPI0000174CD2; UNIPARC:UPI0000174CD3

A;Experimental source: strain Long-Evans

C;Genetics:

A;Gene: CYP2B4

C;Superfamily: human cytochrome P450 CYP2D6; cytochrome P450 homology

C;Keywords: chromoprotein; heme; iron; metalloprotein; microsome; monooxygenase; oxidoreductase; transmembrane protein

F;312/Binding site: heme iron (Cys) (axial ligand) #status predicted

Query Match 5.1%; Score 6; DB 2; Length 367;

Best Local Similarity 100.0%; Pred. No. 5.4e+02;

Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps

0;

Qy 98 AVIEPI 103

|||||

Db 102 AVIEPI 107

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**Williams et al (Biochemistry 31: 9768 (1992))****RESULT 636****A44374**3-carboxy-cis,cis-muconate cycloisomerase (EC 5.5.1.2) - *Pseudomonas putida*

N;Alternate names: 3-carboxy-cis,cis-muconate lactonizing enzyme

C;Species: *Pseudomonas putida*

C;Date: 10-Mar-1994 #sequence\_revision 10-Mar-1994 #text\_change 09-Jul-2004

C;Accession: A44374

R;Williams, S.E.; Woolridge, E.M.; Ransom, S.C.; Landro, J.A.; Babbitt, P.C.; Kozarich, J.W.

**Biochemistry 31, 9768-9776, 1992**A;Title: 3-Carboxy-cis,cis-muconate lactonizing enzyme from *Pseudomonas putida* is homologous to the class II fumarase family: a new reaction in the evolution of a mechanistic motif.

A;Reference number: A44374; MUID:93003135; PMID:1390752

A;Accession: A44374

A;Status: preliminary

A;Molecule type: DNA

A;Residues: 1-407 &lt;WIL&gt;

A;Cross-references: UNIPROT:P32427; UNIPARC:UPI00001313BA; GB:L17082;

NID:g309875; PIDN:AAA25920.1; PID:g309876

A;Note: sequence is inconsistent with the nucleotide translation

A;Note: sequence extracted from NCBI backbone (NCBIN:115904, NCBIP:115905)

C;Superfamily: fumarate hydratase

C;Keywords: amidine-lyase; carbon-nitrogen lyase; intramolecular lyase; isomerase; purine nucleotide biosynthesis

Query Match 5.1%; Score 6; DB 2; Length 407;

Best Local Similarity 100.0%; Pred. No. 5.8e+02;

Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps

0;

**Qy 74 QAQVIA 79**

|||||

**Db 340 QAQVIA 345**



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Horie et al (Biochemistry 106: 1 (1989))

## RESULT 840

JU0033

hypothetical L1 protein (third intron of gene TS) - human

C;Species: Homo sapiens (man)

C;Date: 07-Jun-1990 #sequence\_revision 07-Jun-1990 #text\_change 31-Dec-2004

C;Accession: JU0033

**R;Horie, N.; Nalbantoglu, J.; Kaneda, S.; Ayusawa, D.; Seno, T.; Takeishi, K. J. Biochem. 106, 1-4, 1989**

A;Title: Identification and characterization of an L1 family sequence with a very long open reading frame in the third intron of the human thymidylate synthase gene.

A;Reference number: JU0033; MUID:89380111; PMID:2476429

A;Accession: JU0033

A;Status: nucleic acid sequence not shown

A;Molecule type: DNA

A;Residues: 1-562 &lt;HOR&gt;

A;Cross-references: UNIPROT:O00378; UNIPARC:UPI00001785F5

A;Note: this sequence is similar to human teratocarcinoma L1 RNA species and RNA dependent DNA polymerases of various origins

Query Match 5.1%; Score 6; DB 2; Length 562;  
Best Local Similarity 100.0%; Pred. No. 7.6e+02;  
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps  
0;

Qy	109	QKLEAF	114
Db	135	QKLEAF	140

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Rosel et al (J. Virol. 56: 830 (1985))

RESULT 873

FOVZZW

major core protein P4b precursor - vaccinia virus (strain WR)

C;Species: vaccinia virus

C;Date: 30-Jun-1987 #sequence\_revision 30-Jun-1987 #text\_change 09-Jul-2004

C;Accession: A03871

R;Rosel, J.; Moss, B.

J. Virol. 56, 830-838, 1985

A;Title: Transcriptional and translational mapping and nucleotide sequence analysis of a vaccinia virus gene encoding the precursor of the major core polypeptide 4b.

A;Reference number: A03871; MUID:86062913; PMID:2999438

A;Accession: A03871

A;Molecule type: DNA

A;Residues: 1-643 &lt;ROS&gt;

A;Cross-references: UNIPROT:P06440; UNIPARC:UPI0000138C37; GB:M11079;

NID:g335714; PIDN:AAA48298.1; PID:g335715

C;Superfamily: vaccinia virus major core protein P4b

C;Keywords: core protein

F;1-61/Domain: leader peptide #status predicted &lt;LDR&gt;

F;62-643/Product: major core protein P4b #status predicted &lt;MAT&gt;

Query Match 5.1%; Score 6; DB 1; Length 643;  
 Best Local Similarity 100.0%; Pred. No. 8.5e+02;  
 Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps  
 0;

Qy 67 QAAPYI 72  
 |||||  
 Db 382 QAAPYI 387

Thus, each of the polypeptides is embraced by the claims.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Flores et al (Nucleic Acids Re. 18, 901 (1990)), Shuldiner et al (J. Biol. Chem. 264: 9428 (1989)), Yuan et al (Proc. Natl. Acad. Sci. USA 80: 1169 (1983)), Williams et al (Biochemistry 31: 9768 (1992)), Horie et al (Biochemistry 106: 1 (1989)), or Rosel et al (J. Virol. 56: 830 (1985)) in view of applicants' admitted state of the prior art (*e.g.*, instant application at pages 42-44). Each of the primary references discloses a

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polypeptide that shares at least 5 contiguous amino acids with the polypeptides mentioned in the claims.

See the alignments above and the rejection under 35 U.S.C. § 102(b) hereinabove. Applicants acknowledge the production of antibodies to be old (see instant application at pages 42-44, especially page 43, lines 12-21). It would have been obvious for one of ordinary skill in the art at the time the invention was made to use any of the polypeptides of the primary references to raise antibodies by the admittedly old methods in order to detect the polypeptides of any one of the primary references.

Claims 78-85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

**OFFICIAL FAX NUMBER**


The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

2/28/04